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System Demo 2022 Q3 Q&A

Date: 28 September 2022

Location: Online, 09:00 - 12:30 Amsterdam time (CEST)

Link: Quarterly system demo - Q3 2022 | European Medicines Agency (europa.eu)

Disclaimer

Below is a direct record of all questions asked through Slido.com during the System Demo and answers provided in writing. Questions not asked through Slido.com are not captured. Questions that have no written answers below where either responded to verbally or did not receive a response during the System Demo event. In principle this document will not be updated. Generally the order of questions answered follows the order in which they were prioritised by the audience using the "thumbs up" feature of Slido.com The responses represent the expert view of the development teams at the time of the Demo and are not official statements by the European Medicines Agencies or it partners.

Electronic Product Information (ePI) – Product Lifecycle Management Value Stream

Question	Reply
Are the timelines for ePI portal available and where to find them?	We are planning a pilot in the second half of 2023 with CAPs and some NAPs. The outcome of the pilot will inform the roadmap. Following the pilot we will move to implementation phase for EMA-CAPs and early adopter NCAs.
Are you planning to include SPOR data in the ePI portal in order to allow less duplication of information being added? Also, do you have any plans to autosuggest edits, to make it easier to fill in? (list of side effects for example)	In the MVP, the main link between the ePI and SPOR will be the PMS ID. Through the PMS ID in future all the master data could be accessed. We intend to fully maximise the use of SPOR data, however this will not be the case in the MVP and we will move towards this in a stepwise way. The MVP will have limited features. Advanced features such as editing support as you mention will be for future developments. As per the Agile methodology, we start with an MVP and continually improve.

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Can we create an ePI off-line without using the ePI portal? All our digital workflows end at the doorstep of EMA, where we are forced to re-type the information we already have in our systems (DADI, now ePI).	Yes, it will be possible to upload your FHIR ePI that you make yourself to the portal.
Can you add track-changes? (for reviewing/assessment purposes) Or should working documents still be submitted?	Track changes will not be available in the MVP, it would be certainly a desirable feature for later development.
Does it work in Greek and Cyrillic (Bulgarian)?	We have tested rich text editors to include in the portal and indeed the portal will work for Greek/Cyrillic, this is a must have.
Everybody participating in the creation of the ePI (also translators for different languages) will need an EMA/ePI account I assume.	The applicant can decide how to organise the creation of ePI and can indeed have EMA/ePI accounts for translators so that they could be 'co-authors'.
I see the tendency to work on EMA platforms which completely messes up the internal, company document life-cycle. This means a significant increase of the workload, at least initially, before figuring out how to deal with this new set-up.	We are working at the moment on the MVP, and will hope to add features to facilitate you in future, such as an API for upload. We will introduce ePI with comprehensive consultation to ensure stakeholders have time to prepare.
Is an export to pdf format foreseen?	We will be exploring Export in the coming months, including export to pdf.
Is it expected to have 1 ePI per Medicinal Product (Name, Form, Strength), or the capability to repeat the SmPC sections 1-10 for the different forms and strengths like in Word/PDF today?	The ePI will be the same as it is today, just in electronic format.
Is it possible to upload word/pdf file so the system automatically divide text into sections?	It will be possible to upload FHIR files in the MVP, not word/pdf.
Will the API allow ePIs to be created from the MAH's own IT applications (e.g RIM/labelling system)?	In the MVP, it will be possible to upload a FHIR ePI to the portal. Further integration with MAH systems is certainly a priority for the future.
Would ePI support collaborative editing, including audit trail of who entered what, no unnoticed overwriting... (cf. the tracked changes question)	This would not be in the MVP, but a future development.
You said that the ePI is created section by section. There is quite some repetition between labeling and SmPC, or SmPC and PI, or different strengths. Any way to re-use text portions? Or type everything multiple times?	Indeed, we will allow duplication of documents, we hope to demo that in future.

Variations for Human Electronic Application web-form (eAF) aka "DADI" & Product Management Services (PMS) – Product Lifecycle Management Value Stream

Question	Reply
Can we select some packages within a product to apply a variation, instead of doing it on all packages at once? Currently, checkboxes against packages appear disabled.	Yes, it is possible to select only the relevant/impacted packages/presentations. This is done in the Present and Proposed section where the scopes and Packaged medicinal products are linked. The checkboxes in the initial product selection screen are disabled as the linking takes place later, in this view the list of packages is just for identification of the correct medicinal product.
Can you please inform us if we can already apply to participate in the second UAT of DADI eAF And if yes can you please give us short information on how to apply?	The registration for the second external UAT will be opened at a later stage and information on the details on how to register will be published on the eSubmission website.
Full screen not working on Youtube.com also; showing video is not available.	Sorry to hear about this. YouTube allows full screen when I test it. You will still see the Webex frame though. https://www.youtube.com/watch?v=gP6jIw7pHzE
Hello. There is some improvement in performance of the DADI form, however it is still taking very long to complete the form (2-3times longer as currently). I hope the performance will still improve?	We are working on the performance of "Add product". The other screens should load faster now. Once we go to production we expect the performance to increase a bit more
In addition to the 2 cases cited during the Demo (Spain - MA# for form/dose level ; Italy - MA# at presentation level), it would be needed to cover the multi-lingual aspects (Belgium and Finland)	This is also covered in the Deltas. For the moment we have just demoed this use case, but there are other use cases that have been taken into account (i.e.: nullifications, invalidations, etc etc)
In Spain, the MA# is at form/dose level, so why is it migrated at the Package level (as seen on the HTML viewer) instead of the Medicinal Product level?	What we have shown in the demo is a use case when two records for the same medicinal product but different presentations are generated. Therefore, one Medicinal Product is created with two different packsizes
In your PMS example you assume all but pack size is identical. What if your 4 PRD codes are inconsistent in QPPV, or contact phone number? How does the PMS import solve this?	xEVMPD deltas will overwrite the data with the last record submitted. So the last QPPV info in this case will be shown in PMS.
Is it possible to export a list with all Medicinal Products? If it's not possible, how do you recommend industry map their RIMs with PMS IDs?	This is not in scope for the variation forms, but please make sure the requiremet reaches our colleagues from the SPOR task force and PMS teams. Of course we can also mention it to them

Is it possible to include tables or screen captures into the present & proposed?	Yes, both can be added in the present and proposed section. We are working to improve the editing features even further, the current fields allow copy/paste of plain text only so tables will need to be created in the fields themselves for now. Images can be added as necessary.
Is it possible to prepare "draft" applications if you have e.g. national registrations and need to prepare separate variations for each national registration in each country. Or do you have to create a submission from scratch every time?	At the go-live the form can initially be only used for Centralised Procedure applications (i.e. for CAPs only). It is possible to create as many draft applications as needed however, the 'copy application' feature is not yet available.
Is there already an idea/strategy how pack size then will be populated for all non-CAPS? As there is no SIAMED for them.	As you have seen in the demo, there won't be any information of pack size coming from xEVMPD (as we don't have this info there). Only data of pack description will be available. It is already known that missing data will have to be provided, and EMA is working on the capability to provide missing data in the future.
Is this list of products (Product selection) linked to the account or to the MAH?	The list of products available is linked to the MAH you are associated with i.e. the form author needs to be associated to the MAH that 'owns' the specific products.
Pack sizes information is not part of xEVMPD. I assume it comes from SIAMED. How to I correct mistakes fast? Still via Service Now (meaning open a ticket)?	Correct, for CAPs this information is indeed currently coming from Siamed. If you notice an issue with your product, the fastest and easiest way for the MAH is to contact the EMA Procedure Manager via email directly.
The updated layout is much more appealing and seems clearer than the previous one.	Thank you
Unable to see on full screen on youtube once clicked on Full screen.	I noticed that too. We'll look into it. For now on youtube.com itself you should be able to go to full screen mode.
What if a "Full name" is not unique, because it is a trade name and the same over multiple authorisations? How do I identify my product then?	Currently, indeed it may be in some cases difficult to initially identify the medicinal product you wish to select if there are more than one and the full name is the same. We are looking at different ways to improve this in future, however, for now, the workaround solution is to view the products from the SPOR menu and if this doesn't help, you can select both (or all if more than 2), products in the form and save. This will allow you to expand the product view to see the presentations with the related MA numbers and then you can note down the PMS id which is unique. You can then move back to the product selection menu to remove the product you don't need. Details on how to do this are available in the user guide (portal navigation menu).

What is relationship between ePI and PMS/DADI?	We all use PMS as the source for product information - and now we share a Portal, so there is only 1 URL to go to
Will product changes submitted via DADI forms be update into Siamed/PMS by EMA, or are updates only driven by XEVMPD submissions and scope?	The variation update to PMS will take another year to develop. Until then we have to work with xEVMPD submissions.
Will the FHIR viewer be available to MAHs?	No. This is an internal tool used by us to see the product data. A User Interface will be delivered to show the PMS data to applicants.
Will there be any update on the PMS?	The PMS is presenting now.
Will there be any updates to the XEVMPD requirements related to what we're seeing on screen (i.e. having one EV code per pack size rather than MA)?	We can't change the legal requirements of xEVMPD. Therefore, only one record is needed for MA. Nevertheless, it is already foreseen in the xEVMPD guidelines that information at pack size can be submitted. In cases were the data is already in xEVMPD, it will be migrated to PMS. Otherwise, data will have to be submitted to PMS directly once the capability to do so is available.

European Shortages Monitoring Platform (ESMP) / Shortages Management for Medicinal Products – Monitoring Value Stream

Question text	Reply
Do you anticipate to connect ESMP with EMVS?	
there is always a common theme - CAP's data only; and this is a minority of the available products	
for notifying shortages, we need to be registered as iSPOC in IRIS. but does it mean that all shortages notifications will have to be performed on ESMP and not IRIS?	
Will the list of products for reporting shortages in ESMP only contain those on the critical medicines list?	
sorry if I missed the answer, but when will ESMP be available for MAHs? and during this period of time, how should we manage this?	
Would ESMP take information about Marketing Status, to limit the selection of countries for which there is a shortage? From where the Marketing Status would be retrieved? From IRIS? From SPOR PMS?	
Will you make available the content of the lookup/dropdown menues, so for industry to use offline when preparing submissions?	

It seems that ESMP requires a certain level of information to be ready in PMS. Is there clear requirements shared with the SPOR PMS Team, and by when ESMP would expect PMS to be fully ready/functional?	
Can you already demonstrate the NCA notification screen of ESMP?	
Lists of specific medicines for health crises will be issued (e.g. Covid-19). However, the drug shortage itself could cause this emergency situation. Could you please explain these MAH obligations and approach briefly, if definable?	
would you please confirm that routine shortage notification out of crisis period are not to be performed through IRIS	
In case of non CAP medicinal products, pack sizes can be different in the member states. How will you add this information in ESMP?	
How to get access to APi?	